

# DRI<sup>®</sup> Methadone Metabolite Urine Calibrators

**IVD** For In Vitro Diagnostic Use Only

## Rx Only

- REF** 1664 DRI Negative Calibrator (10 mL)  
 1388 DRI Negative Calibrator (25 mL)  
 100117 DRI Methadone Metabolite 150 ng/mL Calibrator (10 mL)  
 100118 DRI Methadone Metabolite 300 ng/mL Calibrator (10 mL)  
 100120 DRI Methadone Metabolite 1000 ng/mL Calibrator (10 mL)  
 100122 DRI Methadone Metabolite 2000 ng/mL Calibrator (10 mL)

## Intended Use

DRI<sup>®</sup> Methadone Metabolite Urine Calibrator Kits are intended for the calibration of the DRI Methadone Metabolite Assay.

## Description of the DRI Methadone Metabolite Urine Calibrators

DRI Methadone Metabolite Urine Calibrators are human urine-based and ready-to-use. They are prepared by spiking negative urine matrix with respective quantities of 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP). The concentration of EDDP in each calibrator is validated by a GC/MS methodology.

## ⚠️ Precautions and Warning

The DRI Methadone Metabolite Urine Calibrators are for in vitro diagnostic use only. They are harmful if swallowed.

**DANGER:** DRI Methadone Metabolite Urine Calibrators contain  $\leq 0.3\%$  bovine serum albumin (BSA).

H317 - May cause allergic skin reaction.

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Avoid breathing mist or vapor. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/eye protection/face protection. In case of inadequate ventilation wear respiratory protection. If on skin: Wash with plenty of soap and water. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If skin irritation or rash occurs: Get medical advice/attention. If experiencing respiratory symptoms: call a POISON CENTER or doctor/physician. Wash contaminated clothing before reuse. Dispose of contents/container to location in accordance with local/regional/national/international regulations.

The calibrators contain  $\leq 0.09\%$  sodium azide. Avoid contact with skin and mucous membranes. Flush affected areas with copious amounts of water. Get immediate medical attention for eyes, or if ingested. Sodium azide may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up. Clean exposed metal surfaces with 10% sodium hydroxide.

The calibrators are prepared from non-sterile human urine. **Handle the calibrators as if they were potentially infectious.** Do not use the calibrators beyond their expiration dates printed on their respective labels.

## Storage

Calibrators should be stored refrigerated. The calibrators opened or unopened, are stable until the expiration date indicated on their labels.

## Calibrator Preparation

The DRI Methadone Metabolite Urine Calibrators are ready-to-use.

## Assay Procedure

For instructions, refer to the instrument specific application sheet for the DRI Methadone Metabolite Assay.

## Results and Expected Values

### Qualitative results

Use 1000 ng/mL Calibrator as a cutoff reference for distinguishing "positive" from "negative" samples. A sample that exhibits a change in absorbance value ( $\Delta A$ ) equal to or greater than the rate obtained with cutoff calibrator is considered positive. A sample that exhibits a change in absorbance value ( $\Delta A$ ) lower than the rate obtained with the cutoff calibrator is considered negative.

### Semi-quantitative results

A rough estimate of drug concentration in the samples can be obtained by running a standard curve and by quantitating samples off the standard curve using all the calibrators.

## Limitations

The DRI Methadone Metabolite Urine Calibrators are designed for use with the DRI Methadone Metabolite Assay.

## Quality Control

All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

## Bibliography

1. Urine Testing for Drug of Abuse. National Institute on Drug Abuse (NIDA) Research Monograph 73, 1986.
2. Mandatory Guidelines for Federal Workplace Drug Testing Program. National Institute on Drug Abuse. Federal Register Vol. 53, No 69, 11970 (1988).
3. DRI Methadone Metabolite Assay Package Insert.
4. Data on traceability are on file at Microgenics Corporation, a part of Thermo Fisher Scientific.

## Glossary:

<http://www.thermofisher.com/symbols-glossary>



Microgenics Corporation  
 46500 Kato Road  
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 US Customer and  
 Technical Support:  
 1-800-232-3342



**EC REP**

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For insert updates go to:  
[www.thermofisher.com/diagnostics](http://www.thermofisher.com/diagnostics)

## Other countries:

Please contact your local Thermo Fisher Scientific representative.

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